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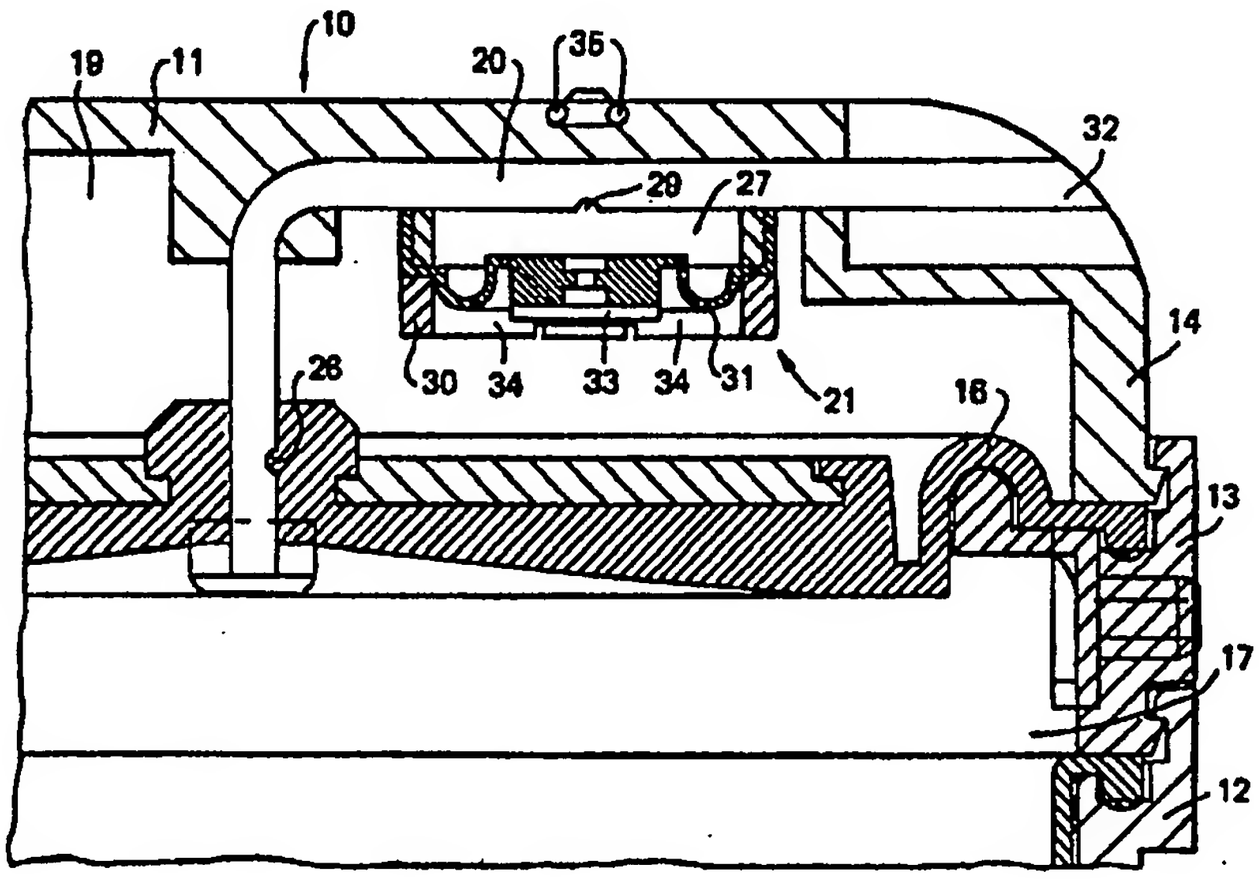

(57) Abstract

A liquid delivery device (10) particularly useful for delivering drugs in a liquid form, comprising a pressure-control chamber (18) having an electrolytic cell (22) therein and a reservoir (17) for the liquid separated from the pressure-control chamber (18) by a displaceable diaphragm (15). When sufficient pressure is generated within the pressure-control chamber (18) and reservoir (19), a second diaphragm (16) is raised to allow liquid to escape from the device, *via* an opening (26), through an outlet tube (20). The device (10) also includes a compensation chamber (19) which adjusts the rate of flow of the liquid in response to variations in ambient temperature and pressure. There is provided a pressure sensor (21) in the form of a sensor chamber (27) for immediately detecting an interruption in the flow of liquid from the device as an increase in pressure in the outlet tube (20) with respect to the pressure within the compensation chamber (19) and hence the reservoir (17). The means (21) for detecting an interruption in the delivery of liquid does not rely on the increase in pressure occurring as a result of continued gas generation.

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Liquid delivery device

Technical Field

The present invention relates to liquid delivery devices and systems, and, in particular, to devices and systems for delivering liquids containing drugs. The drugs may be in solution and/or suspension in a pharmaceutically acceptable medium which is in the liquid state or the drugs may themselves be liquids.

Background Art

Such devices are described in, for example, U.S. Patent Specification Nos. 5,062,834; 5,090,963; 5,186,805; and 5,242,406.

The device described in U.S. Patent Specification No. 5,242,406 comprises an outer housing having an outlet through which liquid is delivered, a displaceable member within the housing defining a first expansible-contractible chamber on one side of the displaceable member for holding a supply of the material to be delivered *via* the outlet, and a second expansible-contractible chamber on the opposite side of the displaceable member. The device further comprises pressure-control means for controlling the pressure produced in the second expansible-contractible chamber, and thereby the rate of flow of the liquid *via* the outlet. The pressure control means may include an electrolytic cell for supplying a gas to the second chamber.

Means are included to minimize or eliminate the sensitivity of the rate of flow of the liquid (which is preferably a drug) *via* the outlet to variations in ambient pressure and temperature.

A disadvantage of such a liquid delivery device is that when the flow of liquid out of the unit is interrupted, the user is not immediately alerted to the interruption in order that corrective measures can be taken speedily.

During normal operations, it may occur that the flow of liquid is unintentionally interrupted. For example, the tube leading from the outlet may develop a kink or may become clogged. It is important to alert the user, or those attending to the user, of the occurrence of such an event since the undetected cessation of the flow of medication could entail highly adverse consequences to the patient's well being.

Although the device described in U.S. Patent Specification No. 5,242,406 is provided, in certain embodiments, with an occlusion alarm for indicating a blockage, the mechanism used to detect the interruption in the flow of liquid does not accomplish the objective of providing an immediate indication of a blockage. This is because the sensor comprises a pressure-sensitive resistor and a contact linked to a diaphragm comprising part of the wall of the pressure-control chamber. An increase in pressure within the chamber results in the exertion of an additional force against the walls of the chamber, such that the diaphragm is pushed outwards and the contact provides increased pressure against the pressure-sensitive resistor. The signal from the pressure-sensitive resistor can be used to trigger an alarm warning.

If a blockage occurs in the device or the outlet tube, the pressure-control chamber is prevented from expanding further, with the result that continued generation of gas leads to an increase in pressure. In time, this is detected by the pressure-sensitive resistor. If the normal operating pressure within the pressure-control chamber is P1 and the pressure at which the alarm is triggered is P2, the time taken for the pressure to increase from P1 to P2 will largely depend on the volume of the pressure-control chamber when the blockage occurs. If the pressure-control chamber has expanded considerably after a long period of operation, then there may be an inordinate delay between the interruption of the flow of liquid and the triggering of the alarm since a relatively large amount of gas will need to be generated in order to provide the required increase in pressure. This may have implications for the health of a patient or the efficacy of the treatment.

There is thus a need for a liquid delivery device and system which can provide an immediate warning that an interruption in the flow of liquid out of the device has occurred.

Disclosure of the Invention

According to the present invention there is provided a device for the delivery of liquid, comprising: an outer housing having an outlet through which the liquid is delivered; a first displaceable member within the housing defining, on one side thereof, an expansible-contractible reservoir for holding a supply of liquid to be delivered *via* the outlet, and on the other side thereof an expansible-contractible pressure-control chamber, pressure control means for controlling the pressure within the pressure-control chamber, thereby controlling the displacement of the first displaceable member which controls, in turn, the rate of flow of the liquid *via* the outlet, means for adjusting the rate of flow of the liquid *via* the outlet to compensate for changes in ambient temperature and pressure, and means for detecting an interruption in the delivery of liquid *via* the outlet comprising a pressure sensor in direct communication with the liquid.

Thus, the detection of an interruption in delivery is not an indirect consequence due to the build-up of gas pressure over time, but is instead a direct consequence of the increase in pressure associated with an interruption of flow of liquid from the device.

The liquid is suitably a liquid containing a drug as hereinabove defined.

Suitably, the means for adjusting the rate of flow of the liquid comprises an expansible-contractible compensation chamber adjacent to the outlet such that expansion of the compensation chamber tends to restrict hydraulic communication between the reservoir and the outlet.

In a preferred embodiment, the compensating chamber and the reservoir are separated by a second displaceable member.

Preferably, the device further comprises an outlet tube connecting the reservoir and the outlet, the pressure sensor being in direct communication with the liquid within the outlet tube.

The pressure exerted by a fluid within a tube is lower if the fluid is in motion through the tube, all other factors being equal. Thus, an outlet tube leading from a pressurised reservoir to the atmosphere will exhibit a pressure gradient along its length. That this is so can be seen from the fact that the liquid moves along the tube in the direction of lower pressure. Therefore, the pressure must be higher within the reservoir than it is within the tube as liquid flows from the reservoir to the tube.

If the tube is blocked, the reservoir and tube form a closed hydraulic system in equilibrium, and so pressure is equal in all parts thereof. Thus, when a blockage has occurred, the pressure of the liquid within the tube equalises with the pressure of the liquid within the reservoir. The equalisation of pressure (that is, the increase in pressure of the liquid within the tube) occurs virtually instantaneously.

It can be seen, therefore, that the provision of a pressure sensor in direct association with the liquid in the outlet tube provides a means for the immediate detection of the interruption of liquid delivery. This is in contrast to the devices of the prior art in which there is necessarily a considerable delay between the occurrence of a blockage and the detection thereof, which delay may diminish the effectiveness of a treatment using such a device.

Further, preferably, the pressure sensor detects the pressure within the outlet tube as a pressure difference between the liquid in the outlet tube and the liquid in the reservoir.

When an interruption has occurred and the reservoir and outlet tube form a closed hydraulic system in equilibrium, the pressures are equal throughout the system. During delivery, however, the liquid is effectively stationary throughout the volume of the reservoir and is

flowing at a considerable rate through the outlet tube, such that the pressure is lower within the outlet tube, as explained above.

Since the pressure of the liquid within the device depends upon, *inter alia*, the external temperature and atmospheric pressure, an increase in the pressure of the liquid within the outlet tube does not necessarily imply that an interruption has occurred (since the same effect may result from a temperature increase). If, however, an increase in temperature causes an increase in the pressure of the liquid within the outlet tube, there will be a corresponding increase in the pressure of the liquid within the reservoir. This means that by measuring the pressure difference between the outlet tube and the reservoir, a far more reliable mechanism is used to detect an interruption in liquid delivery, since such a mechanism is independent of external temperature and pressure variations, depending only on the fact that the pressure in the reservoir is always higher than that in the tube when liquid is flowing.

According to a preferred embodiment, the pressure sensor comprises an expansible-contractible sensor chamber in hydraulic communication with the outlet tube, and the sensor chamber and the compensation chamber are separated by a third displaceable member, such that the displacement of the third displaceable member is dependent upon the pressure difference between the compensation chamber and the sensor chamber.

The term "hydraulic" as used in this specification also embraces the term "pneumatic" except where the context excludes such a meaning. Thus, the pressure sensor may be separated from the outlet tube by a gas-filled space and still be considered to be in hydraulic communication.

If the second displaceable member (between the reservoir and the compensation chamber) is freely displaceable, then the pressure within the reservoir will be equal to that within the compensation chamber. The displacement of the third displaceable member is therefore

dependent on the pressure difference between the sensor chamber (the pressure of which is dependent on the pressure within the outlet tube) and the compensation chamber (the pressure of which is dependent on the pressure within the reservoir).

Thus, when liquid is being delivered *via* the outlet tube, the pressure within the outlet tube (and within the sensor chamber) is lower than the pressure within the reservoir and the compensation chamber. Suitably, and depending upon the configuration of the respective chambers and the characteristics of the displaceable members, the third displaceable member will be in a non-equilibrium position when the liquid is being delivered. When the delivery is interrupted, the pressure is equalised between the outlet tube (and hence the sensor chamber) and the reservoir (and hence the compensation chamber), and the third displaceable member moves to an equilibrium position. The movement of the third displaceable member between the non-equilibrium and equilibrium positions indicates that the delivery of liquid *via* the outlet tube has been interrupted; just as a subsequent displacement of the membrane from the equilibrium position to the non-equilibrium position indicates that the interruption has been removed.

Further, preferably, the third displaceable member includes an electrical conductor such that when the third displaceable member is sufficiently displaced, stretched or relaxed the electrical conductor comes into contact with a pair of contacts, thereby closing an electrical circuit which, in turn, provides an indication of the interruption of liquid delivery.

Any or all of the displaceable members can be selected from diaphragms, impermeable membranes, pistons and elastically or inelastically deformable partitions, most preferably diaphragms.

Preferably, the pressure-control means comprises an electrolytic cell for supplying a gas to said pressure-control chamber.

Preferably, the reservoir is only in hydraulic communication with the outlet when a predetermined reservoir pressure has been reached. Suitably, said hydraulic communication is effected when the displacement of a displaceable member is sufficient to unblock an outlet hole through which hydraulic communication with the outlet is established.

If hydraulic communication between the outlet and reservoir is limited to times at which the reservoir is above a minimum predetermined pressure, then liquid delivery will occur at a more predictable rate (due to the constant head of pressure). A subsequent reduction in reservoir pressure shuts off the supply of liquid, thereby avoiding the problems associated with, for example, an intravenous delivery system in which the liquid is not being actively supplied, in which case the supply of drug is in hydraulic communication with the bloodstream of the patient, allowing intermixing of blood and drug.

Suitably, the device further comprises a liquid delivery filter. This removes any entrained particles in the liquid before delivery to the patient, and may also serve to remove bubbles from the liquid.

Further, preferably the device includes means for delivering the liquid from the outlet to the patient. Suitably, this means comprises a liquid delivery tube having a luer lock at an end thereof.

According to the present invention, the device also includes means for indicating the interruption of liquid delivery when such an interruption has been detected.

Suitably, the device also comprises a display and control unit for controlling the delivery of the liquid from the device and for displaying information regarding the delivery of liquid from the device.

In a preferred embodiment, there is provided a liquid delivery system comprising a liquid delivery device as hereinbefore described

and a display and control unit for controlling the delivery of the liquid from the device and for displaying information regarding the delivery of liquid from the device.

Brief Description of the Drawings

The invention is herein described, by way of example only, with reference to the accompanying Drawings, wherein:

Fig. 1 is a side cross-sectional view of a liquid delivery device according to the present invention;

Fig. 2 is a side cross-sectional view of the device of Fig. 1 taken at right angles thereto;

Fig. 3 is an illustration of a detail of the device shown in Fig. 1;

Fig. 4 is a perspective view of the liquid delivery device of Fig. 1, further including a liquid delivery tube and filter;

Fig. 5 is an exploded view of the various components of the liquid delivery device illustrated in Fig. 4;

Fig. 6 is a top plan view of a display and control unit, typically adapted to be worn on a wrist, such as might be used with the liquid delivery device of Fig. 1;

Fig. 7 is a side elevation of the display and control unit of Fig. 6;

Fig. 8 is a side elevation of the liquid delivery device of Fig. 1;

Fig. 9 is an exploded view of the various components of the display and control unit illustrated in Fig. 6;

Fig. 10 is a side cross-sectional view of an alternative embodiment of a liquid delivery device according to the invention;

Fig. 11 is a schematic representation of a side elevation of certain components of the device illustrated in Fig. 10;

Fig. 12 is a schematic representation of a side elevation of the components illustrated in Fig. 11, when rotated through 90°; and

Fig. 13 is a schematic representation of a side elevation of the components illustrated in Fig. 12, when the liquid is being delivered.

Modes for Carrying Out the Invention

Referring to Figs. 1, 2 and 3, there is shown a drug delivery device, indicated generally at 10, which includes a rigid outer housing 11 which is made of first, second and third sections 12,13,14, all secured together in known manner. Housing sections 12,13,14 are preferably of circular cross-section. A first diaphragm 15 is clamped between the first and second housing sections 12,13. A second diaphragm 16 is clamped between the second and third housing sections 13,14.

It will be seen that first diaphragm 15 divides the interior of housing 11 into an expansible-contractible reservoir 17 on one side thereof and an expansible-contractible pressure-control chamber 18 on the other side thereof. It will be further seen that second diaphragm 16 defines an expansible-contractible compensation chamber 19 between it and housing section 14.

As will be described more particularly below, reservoir 17 serves to hold a supply of a liquid, such as a carrier containing a drug to be delivered; pressure-control chamber 18 serves to control the rate

of delivery of the liquid; and compensation chamber 19 serves to reduce the sensitivity of the delivery rate to variations in ambient pressure and temperature.

Housing section 14 includes an outlet tube 20 mounted therein through which liquid is able to flow from reservoir 17 to the outside. Housing section 14 further includes means, indicated generally at 21 and described in more detail below, for detecting the interruption of liquid delivery though outlet tube 20.

Pressure-control chamber 18 between first diaphragm 15 and housing section 12 controls the displacement of second diaphragm 16 according to the pressure produced within chamber 18, and thereby the rate of flow of the liquid from reservoir 17 to the outlet through outlet tube 20. For this purpose, pressure-control chamber 18 includes an electrolytic cell 22, having a pair of electrodes 23 separated by an electrolyte 24 capable of generating a gas within chamber 18 according to the electrical current passing through cell 22. Electrolyte 24 is disposed within chamber 18, whereas electrodes 23 pass outwardly through housing section 12 to enable them to be connected to an external electric supply, e.g., a battery with a controlling microprocessor.

The drug delivery device illustrated in Figs. 1-3 operates as follows: Reservoir 17 is first completely filled with the liquid containing the drug to be dispensed. This can be achieved by the manufacturer, or alternatively by the doctor or pharmacist, by injection though an injection plug 25 (Fig. 2). As the injection progresses, there comes a point when reservoir 17 becomes nearly filled with liquid. At this point, further injection of liquid serves to raise second diaphragm 16. When diaphragm 16 has been sufficiently upwardly displaced, an opening 26 in outlet tube 20 is uncovered permitting liquid to flow from reservoir 17 to outlet tube 20. Further injection then serves to fill outlet tube 20 which is in direct communication with a sensor chamber 27 (Fig. 2). Once outlet tube 20 is filled with liquid, further injection causes liquid to leave the device

10, providing a visual indication that the device 10 is now completely full of the liquid and is ready for use.

When the drug is to be delivered to a patient, electrodes 23, which are connected to a power supply, such as a battery 28 (Fig. 1), are energized so that an electric potential is applied to electrolyte 24 (Fig. 2) within pressure-control chamber 22. The gas generated in chamber 22 as a result of electrochemical reactions displaces first diaphragm 15 upwards, thereby forcing out liquid from reservoir 17, *via* outlet tube 20, at a rate which is related to the rate of gas generation in pressure-control chamber 22.

The rate of delivery of the liquid from reservoir 17 is affected not only by the rate of gas generation within pressure-control chamber 22 but also by the ambient temperature and pressure prevailing at the time the device 10 is operated. Variations in the ambient temperature and pressure can be compensated for as described hereinafter.

An increase in temperature will increase the pressure in pressure-control chamber 18 and *via* diaphragm 15 also increase the pressure in liquid-filled reservoir 17, tending to increase the rate of delivery of the drug. To compensate for the increased pressure in reservoir 17, an air-filled compensation chamber 19 is provided. An increase in temperature will also increase the pressure in compensation chamber 19 tending to substantially compensate for the increase in pressure in reservoir 17.

It should be noted that diaphragms 15 and 16 are both freely displaceable, such that the pressure is equalised between reservoir 17, pressure-control chamber 18 and compensation chamber 19. These three compartments form a system in which the pressure is effectively equalised throughout.

To alert the user or those attending the user of the interruption of the flow of liquid out of the device, the device is equipped with

means 21 for detecting the interruption of liquid delivery through outlet tube 20.

Referring particularly to Fig. 3, it can be seen that outlet tube 20 is provided with a small hole 29 at an appropriate point along its length. Hole 29 allows hydraulic communication between sensor chamber 27 and outlet tube 20. Sensor chamber 27 is preferably formed within a compartment 30 connected to, or integrally formed with housing section 14. Sensor chamber 27 can be liquid filled or gas filled; in practice, it is likely to be air filled although a small amount of liquid may enter sensor chamber 27 when outlet tube 20 is filled.

In order to properly understand the principles of operation of sensor chamber 27, it is necessary to consider the pressures within the various compartments of the device and the pressure differences across the various displaceable members.

Firstly, it has already been noted above that reservoir 17, pressure-control chamber 18 and compensation chamber 19 are all separated from one another by freely displaceable membranes, thereby ensuring that the pressures are equalised within each chamber. This is apparent from the fact that a pressure difference across a barrier causes a force to be applied in the direction of lower pressure. If the barrier is free to move, it will do so until the pressure is equalised or until it is no longer free to move. Therefore, the reservoir 17, pressure-control chamber 18 and compensation chamber 19 form a single pressure system (the "internal system").

Secondly, sensor chamber 27 is separated from compensation chamber 19 by a third diaphragm 31 which is shown in Fig. 3 in its relaxed position. The diaphragm 31 is relaxed when the pressures within compensation chamber 19 and sensor chamber 27 are equal. It can be seen that if the pressure is greater within compensation chamber 19 than within sensor chamber 27, then diaphragm 31 will be forced upwards until the pressures are equal, until the diaphragm cannot move up any further, or until the elastic nature of the diaphragm supplies a

sufficient resistive force to balance the pressure difference. A subsequent equalisation of pressures will cause the diaphragm 31 to immediately drop back to its relaxed position. The sensor chamber 27 is in hydraulic communication with outlet tube 20 *via* the small hole 29, such that the pressures within outlet tube 20 and sensor chamber 27 are effectively equalised. Thus, the outlet tube 20 and sensor chamber 27 form another single pressure system (the "external system").

Before the device is filled, the internal and external systems are at equal pressures (at atmospheric pressure). The reservoir is filled using injection plug 25; when the reservoir is full, further injection causes second diaphragm 16 to be pushed upwards, with the pressure steadily increasing throughout the internal system. When second diaphragm 16 has been moved upwards to a sufficient extent, opening 26 is uncovered allowing the liquid to escape from reservoir 17 *via* opening 26 and outlet tube 20. The liquid fills outlet tube 20, partially fills the associated sensor chamber 27 (*via* small hole 29) and finally emerges from the outlet tube at open end 32 thereof (the "outlet"). The liquid within reservoir 17 remains under pressure after the injection is completed, since only a miniscule amount of liquid escapes from the newly filled reservoir *via* opening 26 before the corresponding reduction in the volume of liquid in the reservoir 17 allows second diaphragm 16 to drop back by a sufficient amount to cover opening 26, thereby sealing reservoir 17 under pressure.

Although the reservoir 17, pressure-control chamber 18 and compensation chamber 19 remain under pressure when the device is full (since the internal system is sealed), the external system is at atmospheric pressure (since it is open at end 32 of outlet tube 20 to the atmosphere). Therefore, third diaphragm 31 is in the raised position when the device is full, due to the pressure difference between the internal and external systems which is applied across third diaphragm 31.

When gas is generated in pressure-control chamber 18, the corresponding increase in pressure is transmitted throughout the

internal system, forcing second diaphragm 16 upwards by a sufficient amount to uncover opening 26 and allow liquid to escape *via* outlet tube 20. While the pressure increases equally in both reservoir 17 and compensation chamber 19, the liquid filling reservoir 17 is incompressible. It is for this reason that second diaphragm 16 moves upwards reducing the volume of the gas filling compensation chamber 19, which is compressible.

Although the external and internal systems are in hydraulic communication when the device is in operation as described above, the pressures do not equalise between the two systems since liquid is free to escape from end 32 of outlet tube 20. Thus, the pressure in the internal system remains at the elevated pressure required to uncover opening 26, while the pressure within the external system remains at a lower pressure due to the flow of liquid therethrough. The flow of liquid from the internal to the external system is indicative that the pressure within the external system is lower than that within the internal system. Therefore, third diaphragm 31 remains raised even when the device is in use, since there is always a pressure differential between compensation chamber 19 and sensor chamber 27. Diaphragm 31 will only drop back to its relaxed position when the pressures equalise between the internal and external systems. This only happens if the internal and external systems are in hydraulic communication with no net flow of liquid therefrom.

The equalisation of pressures occurs when the external system suffers a blockage, such as a kink in a delivery tube (not shown) leading from end 32 of outlet tube 20. In such a case, liquid flow ceases and the internal and external systems, which now form a closed hydraulic system, immediately equilibrate. The equilibration of pressures between the internal and external systems causes third diaphragm 31 to drop to its relaxed position. This effect occurs instantaneously and is not dependent on the generation of further gas within pressure-control chamber 18.

Referring to Fig. 3, it can be seen that third diaphragm 31 is connected to a suitable mobile electrical conductor 33 which is dimensioned to contact fixed electrical contacts 34 mounted onto compartment 30 when third diaphragm 31 is lowered sufficiently. Fixed contacts 34 form a part of an electrical circuit having external terminals 35 which can be linked to an alarm circuit to provide a warning that third diaphragm 31 has dropped.

Thus, whenever a blockage, or occlusion, occurs, the increased pressure in outlet tube 20 and sensor chamber 27 displaces third diaphragm 31 and mobile conductor 33 downward towards the equilibrium position until mobile conductor 33 comes in contact with fixed contacts 34, at which point the circuit is closed and a signal is transmitted to a suitable display and control member, described in more detail below, to warn the user of the interruption of flow. Closing of the circuit may also serve to cut off the electric current through electrolytic cell 22.

The liquid delivery device described above is shown in perspective view in Fig. 4 and in exploded view in Fig. 5. A tube 36 extends from the device, through which liquid from the outer end 32 of outlet tube 20 flows to the point of delivery to the patient. Also shown in Fig. 4 is a filter 37 which serves to filter the liquid to ensure that the liquid, which is delivered to the patient *via* a suitable luer lock 38 for accommodating a needle, is free of particles and the like. Filter 37 is preferably a dual-function device which both serves as an i.v. filter (capable of removing 0.1 μm particles) and vents any air bubbles which might be present. Filter 37 may, for example, be a Pediatric IV Filter made by Filtertek of the U.S. There is also shown a battery housing 39 within which batteries 28 are stacked, as shown in Fig. 1.

The exploded view of the liquid delivery device in Fig. 5 includes a number of components which are also indicated in Figs. 1-4 and which are numbered to correspond with those figures. In addition, there is shown a rigid disk 40 which fits over first diaphragm 16. Rigid disk 40 fits the central area of diaphragm 16, thereby holding

this portion of diaphragm 16 rigid. An increase in pressure causing diaphragm 16 to be displaced upwards therefore has an even and predictable effect since the diaphragm 16 and rigid disk 40 together move with a piston-like action, thereby eliminating any irregularities in the upward displacement of the diaphragm. This may be important since it is desirable to ensure that the pressure within reservoir 17 is always constant when the drug is being delivered, thereby allowing predictable rates of delivery and reliable indications of pressure differences between the internal and external systems. Since the delivery pressure is that pressure at which the centre of the diaphragm 16 unblocks opening 26, rigid disk 40 ensures that the central part of the diaphragm moves upwards at a rate which is dependent on the pressure within reservoir 17, because disk 40 causes the majority of the area of diaphragm 16 to move upwards and downwards at a constant rate.

As indicated in Fig. 5, first diaphragm 15, when relaxed, is of a shape such that reservoir 17 is of minimum volume after manufacture. Filling the reservoir 17 *via* injection plug 25 forces diaphragm 15 downwards so that the volume of reservoir 17 is maximised after filling and the volume of pressure-control chamber 18 is minimised. The reason for this arrangement is that reservoir 17, if air-filled after manufacture, would be unable to accommodate the liquid.

Located near the bottom of the unit is the electrolytic cell 22, which is bounded on the top and at the bottom by a pair of hydrophobic filters 41,42. Electrodes 23 extend from electrolytic cell 22 through an electrode seal 43 and through an insulating sleeve 44 which is housed, along with batteries 28, in battery housing 39 whose bottom portion is closed off by a battery cover 45. Batteries 28 are covered at the top with a cover 46 which carries a pair of electrode contacts 47 and a battery contact 48.

A liquid delivery device according to the present invention is preferably worn on the wrist of the user. Suitably, however, the device may be worn on other body sites *via* a belt, for example. The

liquid delivery device, which is itself preferably disposable, is in the form of a cartridge and is designed to fit into a reusable electronic display and control unit such as the unit illustrated in Figs. 6, 7 and 9. Together, the liquid delivery device and the display and control unit form a liquid delivery system. In Figs. 7 and 8, the delivery device and the display and control unit are shown in side elevation in order to illustrate how the system fits together.

Various display and control units may be envisioned, according to the parameters which need to be controlled and the information which should be displayed for any particular application. The illustrative unit shown in Figs. 6, 7 and 9 includes a display which is capable of showing the flow rate and the cumulative volume of liquid, either alternately or simultaneously. The unit, illustrated generally at 50, includes an up scroll button 51 and a down scroll button 52 for selecting displays, as well as an enter button 53 for entering a parameter. Also included are a start button 54 and a stop button 55 to start and stop the delivery of liquid, as well as an eject button 56 to eject a spent cartridge. The display may feature an indicator to show that a cartridge is attached and that the unit is pumping. Furthermore, the unit may provide a warning of low energy in one of the batteries. Finally, a display and control unit will include means for alerting of an occlusion which may take the form of a visual display and/or an aural alarm.

Shown in Fig. 9 is an exploded view of the typical display and control unit illustrated in Figs. 6 and 7. In addition to the components previously described with respect to Figs. 6 and 7, such a unit preferably includes a pair of wrist straps 57,58 which serve to attach the unit to the wrist of the user. The unit further includes a first contact 59 which is associated with the enter button 53, start button 54 and stop button 55, and a second contact 60 which is associated with the up scroll button 51 and the down scroll button 52. Located below the contacts are an LCD housing 61 and an LCD 62 which are positioned above a printed circuit board (PCB) 63.

Situated below PCB 63 is a battery 64 to power the display and control unit as well as an alarm buzzer 65, both of which rest on a bottom cover 66. Bottom cover 66 includes a battery portion 67 which accommodates cover 46 (Fig. 8), and further includes an occlusion indicator switch 68 which accommodates external terminals 35.

Located immediately below bottom cover 66 is a squeeze ring 69 which serves to eject the liquid delivery device 10 upon the depression of eject button 56. Thus, a display and control unit can be designed to accommodate a "snap-fit" cartridge (i.e. drug delivery device). When the cartridge is spent it can be ejected and a fresh supply of drug, in the form of a new cartridge, can be fitted.

Referring to Fig. 10, there is shown a drug delivery device, indicated generally at 110, similar to that described in relation to Figs. 1-5. Parts indicated in Fig. 10 which are similar to parts indicated in Figs. 1-5 are denoted by reference numerals different from those used in Figs. 1-5 by a factor of 100 (e.g. 10,110; 18,118).

Thus, the device 110 includes a rigid outer housing 111 which is made of first, second and third sections 112,113,114. A first diaphragm 115 is clamped between the first and second housing sections 112,113 and a second diaphragm 116 is clamped between the second and third housing sections 113,114.

The first diaphragm 115 divides the interior of housing 111 into an expansible-contractible reservoir 117 on one side thereof and an expansible-contractible pressure-control chamber 118 on the other side thereof. The second diaphragm 116 defines an expansible-contractible compensation chamber 119 between it and housing section 14.

In similar manner to the device indicted in Figs. 1-5, the device 110 includes an outlet tube 120 and an electrolytic cell 122, and a sensor chamber 127, which operates in exactly the same manner as the sensor chamber previously described.

Outlet tube 120 is provided with an opening 126 through which liquid escapes from reservoir 117. Diaphragm 116, however, is of a different construction to diaphragm 16 illustrated in relation to Figs. 1-5. In the centre of the diaphragm there is an outlet chamber 170 into which outlet tube 120 projects. Outlet chamber 170 forms a tight seal with housing section 114 around the point where outlet tube 120 projects from housing section 114. Outlet chamber 170 is formed in a single piece with diaphragm 116 from a deformable material. The outlet chamber 170 has deformable side walls 171 and a base section 172 provided with two slits 173. In equilibrium, the slits are closed and outlet tube 120 is isolated from reservoir 117. When the device is filled, as described in relation to the device illustrated in Figs. 1-5, liquid is injected into the reservoir until the reservoir is full. Further injection causes diaphragm 116 to be pressed upwards. When diaphragm 116 is pressed upwards, deformable walls 171 partially collapse and base section 172 moves upwards to contact end 174 of outlet tube 120. Further increased pressure within reservoir 117 causes a further upward pressure to be exerted on diaphragm 116 such that slits 173 are distended and allow liquid to fill outlet chamber 170 and to escape, *via* outlet 126 to outlet tube 120 and sensor chamber 127.

When filling stops, the second diaphragm 116 drops back slightly, allowing base section 172 to relax and slits 173 to seal. Thus, in a similar manner to the previously described device, hydraulic communication is only effected between the reservoir 117 and the outlet tube 120 when a predetermined reservoir pressure has been reached.

A rigid disk 140 is adhered to the top of diaphragm 116 to provide it with a piston-like action similar to that previously described.

In Fig. 11, there is indicated, generally at 175, certain components of the device of Fig. 10, viewed in a schematic representation of a side elevation, in order to better illustrate diaphragm 116, outlet chamber 170, rigid disk 140 and outlet tube 120.

The diaphragm 116 is view at 90° to the direction in which the cross-section of Fig. 10 is viewed. Thus, only one slit 173 is visible. Broken lines show the cross-section through the centre of diaphragm 116, outlet chamber 170 (defined by side walls 171 and base section 172) and outlet tube 120.

In Fig. 12, the same schematic representation of components is used, but the view is along the same direction as the cross-section viewed in Fig. 10 (and at 90° to the elevation viewed in Fig. 11). Thus, both slits 173 are visible in part.

In Fig. 13, the same components are illustrated as in Fig. 12, although the components are viewed as the liquid is being delivered from the reservoir area, indicated generally at 117, *via* the outlet chamber 170 to the outlet tube 120. The diaphragm 116 is forced upwards, as indicated by the arrows, such that edge portions 176 (not adhered to rigid disk 140) are stretched to allow upward movement of the disk 140, associated central portion 177 and outlet chamber 170. Base section 172 of pressure chamber 170 is prevented from rising when it meets end 174 of outlet tube 120. The outlet chamber 170, being elastically deformable as in the case of diaphragm 116, stretches in response to the upward force, thereby distending the slits 173 and allowing hydraulic communication to be established between the reservoir 117 and the outlet chamber 170 for delivery *via* the outlet tube 120. The liquid is forced out of the outlet tube 120 due to the higher pressure in reservoir 117 than in outlet chamber 170 or outlet tube 120.

As the two illustrative examples show, ensuring that hydraulic communication is only effected when a predetermined reservoir pressure has been reached is an objective which may be achieved in a number of ways. The mechanism actually used is a matter of choice which may depend on circumstances. Thus, if the choice of materials used for the diaphragm 16,116 and outlet tube 20,120 might lead to friction, the first embodiment 10 illustrated in Figs. 1-5 may be unsuitable as there would be a chance of the diaphragm jamming, so

that the second embodiment 110 illustrated would be more suitable. Other circumstances may render the first embodiment or an alternative embodiment most suitable.

Claims: -

1. A device for the delivery of liquid, comprising an outer housing having an outlet through which the liquid is delivered; a first displaceable member within the housing defining, on one side thereof, an expansible-contractible reservoir for holding a supply of liquid to be delivered *via* the outlet, and on the other side thereof an expansible-contractible pressure-control chamber, pressure control means for controlling the pressure within the pressure-control chamber, thereby controlling the displacement of the first displaceable member which controls, in turn, the rate of flow of the liquid *via* the outlet, means for adjusting the rate of flow of the liquid *via* the outlet to compensate for changes in ambient temperature and pressure, and means for detecting an interruption in the delivery of liquid *via* the outlet comprising a pressure sensor in direct communication with the liquid.

2. A device according to Claim 1, wherein the means for adjusting the rate of flow of the liquid comprises an expansible-contractible compensation chamber adjacent to the outlet such that expansion of the compensation chamber tends to restrict hydraulic communication between the reservoir and the outlet.

3. A device according to Claim 2, wherein the compensating chamber and the reservoir are separated by a second displaceable member.

4. A device according to any one of Claims 1-3, further comprising an outlet tube connecting the reservoir and the outlet, the pressure sensor being in direct communication with the liquid within the outlet tube.

5. A device according to any preceding claim, wherein the pressure sensor detects the pressure within the outlet tube as a pressure difference between the liquid in the outlet tube and the liquid in the reservoir.

6. A device according to Claim 5, wherein the pressure sensor comprises an expansible-contractible sensor chamber in hydraulic communication with the outlet tube, and wherein the sensor chamber and the compensation chamber are separated by a third displaceable member, such that the displacement of the third displaceable member is dependent upon the pressure difference between the compensation chamber and the sensor chamber.

7. A device according to Claim 6, wherein the third displaceable member includes an electrical conductor such that when the third displaceable member is sufficiently displaced, the electrical conductor comes into contact with a pair of contacts, thereby closing an electrical circuit which, in turn, provides an indication of the interruption of liquid delivery.

8. A device according to any preceding claim, wherein any or all of said displaceable members are selected from diaphragms, impermeable membranes, pistons and elastically deformable partitions.

9. A device according to any preceding claim, wherein said pressure-control means comprises an electrolytic cell for supplying a gas to said pressure-control chamber.

10. A device according to any preceding claim, wherein the reservoir is only in hydraulic communication with the outlet when a predetermined reservoir pressure has been reached.

11. A device according to any preceding claim, further comprising a liquid delivery filter.

12. A device according to any preceding claim, further comprising means for delivering the liquid from the outlet to a patient.

13. A device according to any preceding claim, further comprising means for indicating the interruption of liquid delivery when such an interruption has been detected.

14. A device according to any preceding claim, further comprising a display and control unit for controlling the delivery of the liquid from the device and for displaying information regarding the delivery of liquid from the device.

15. A liquid delivery system comprising a liquid delivery device according to any one of Claims 1-14 and a display and control unit for controlling the delivery of the liquid from the device and for displaying information regarding the delivery of liquid from the device.

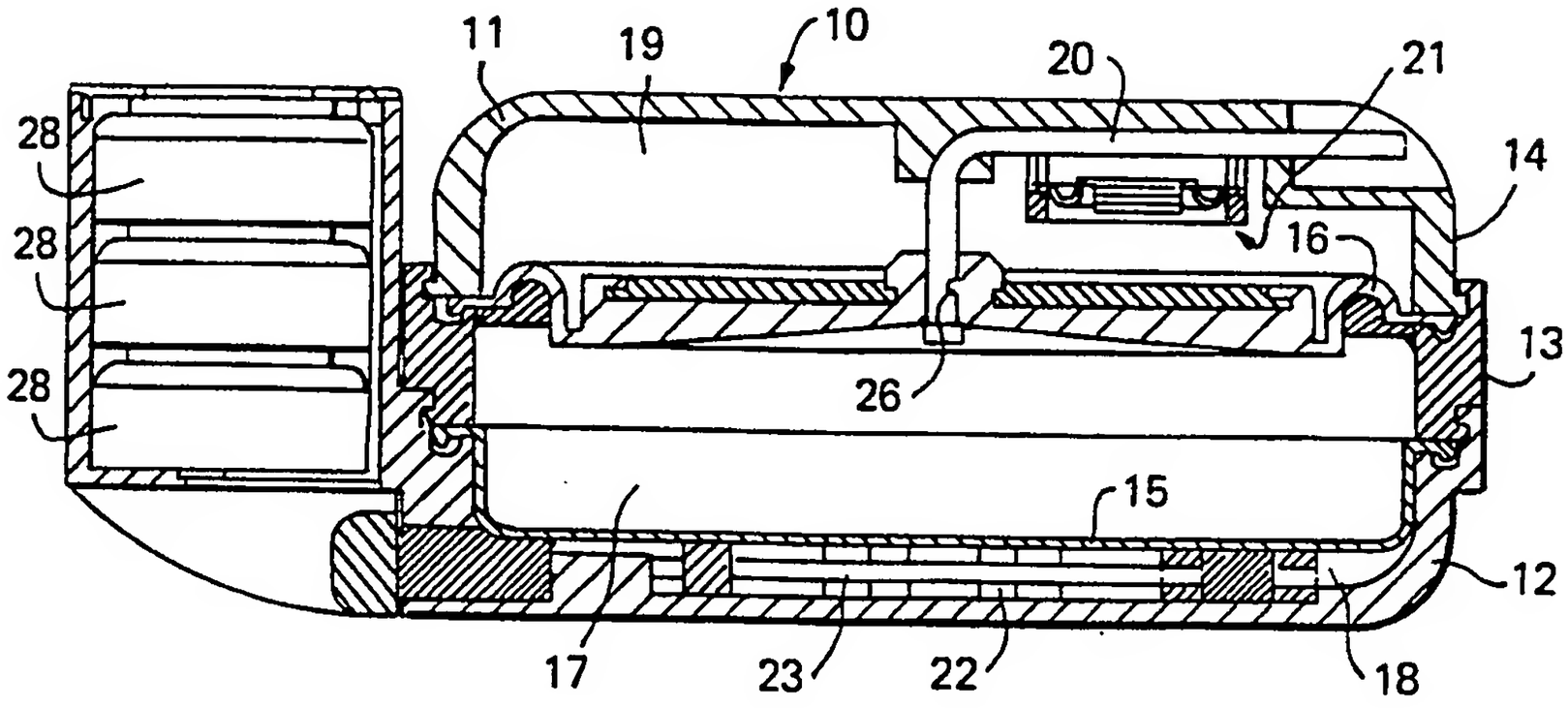

FIG. 1

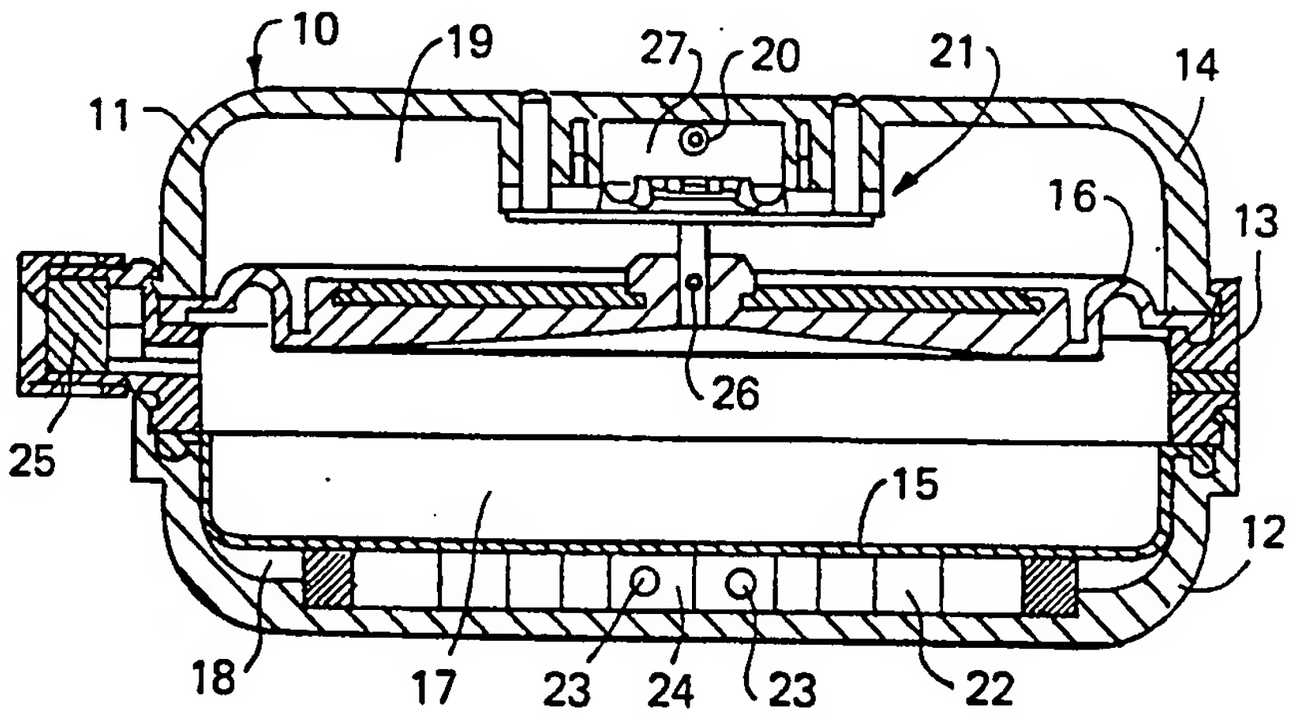

FIG. 2

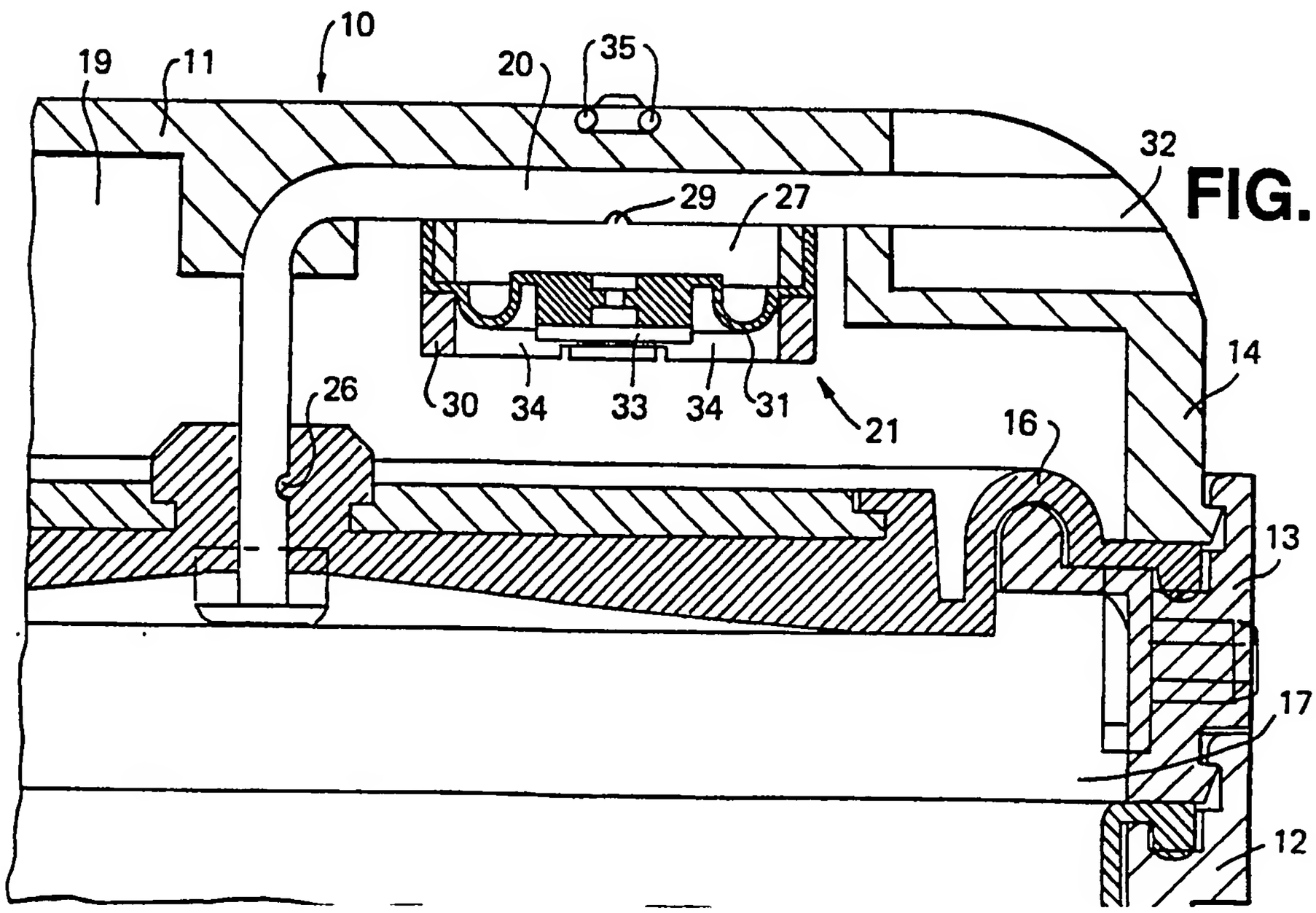

FIG. 3

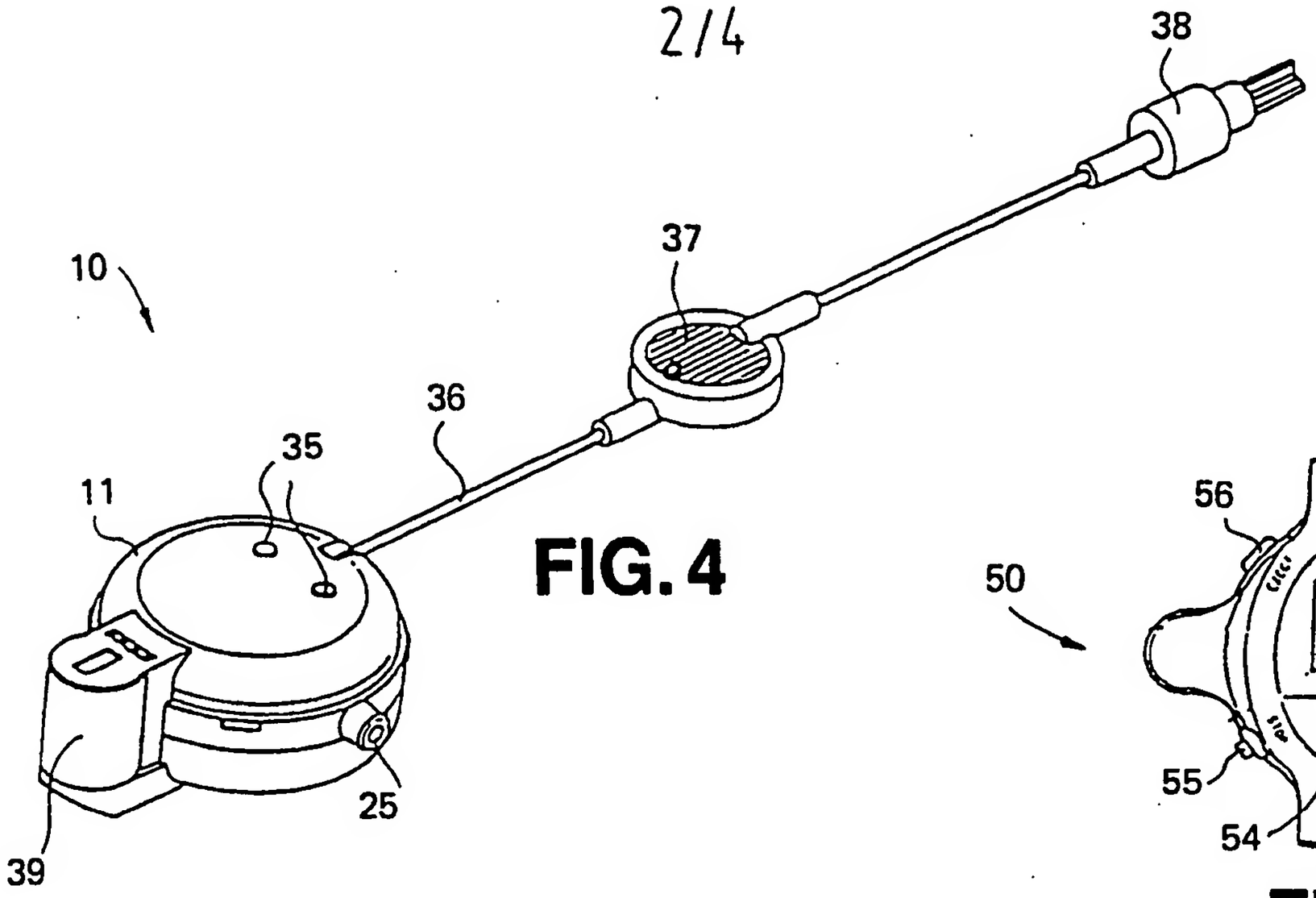

FIG. 4

FIG. 6

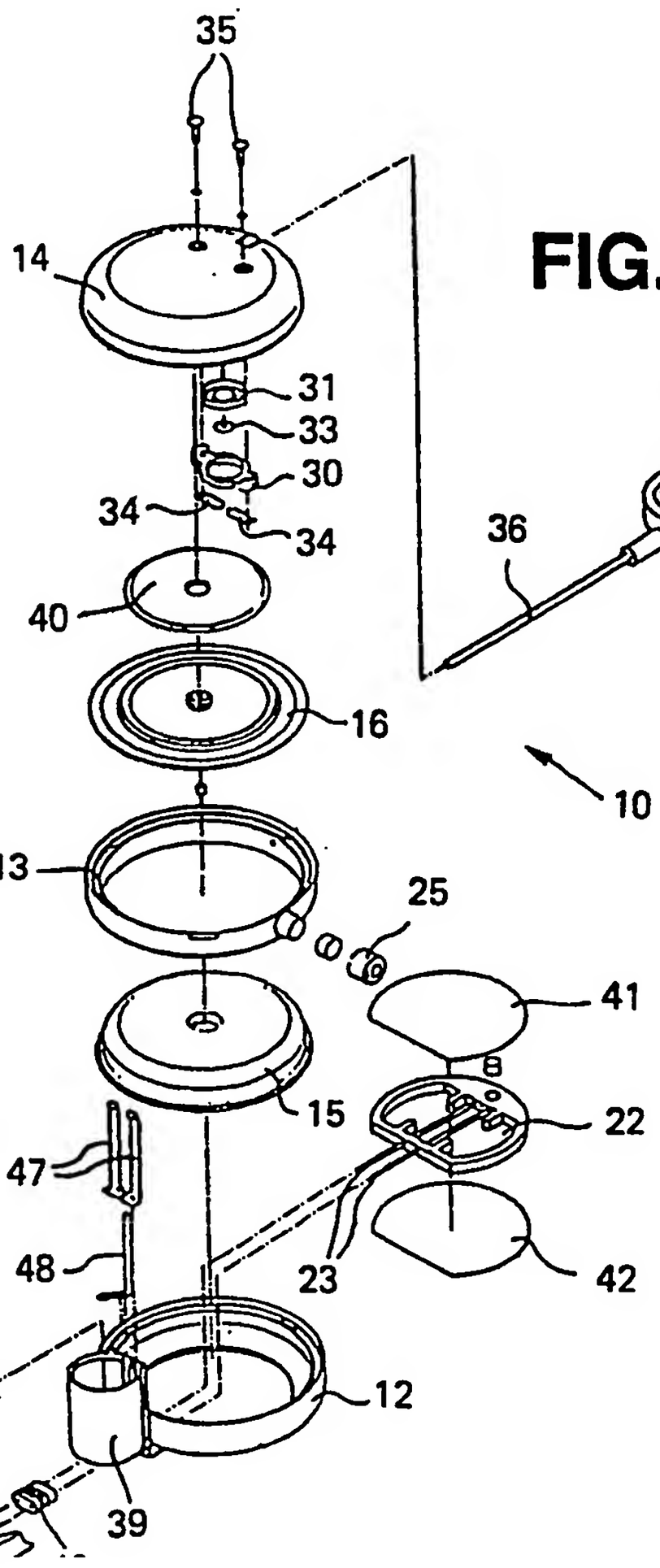

FIG. 5

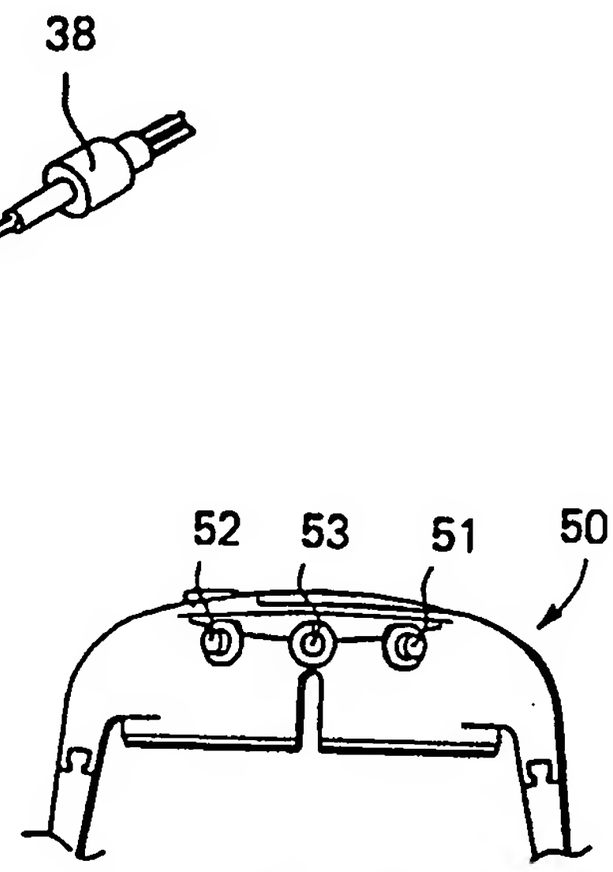

FIG. 7

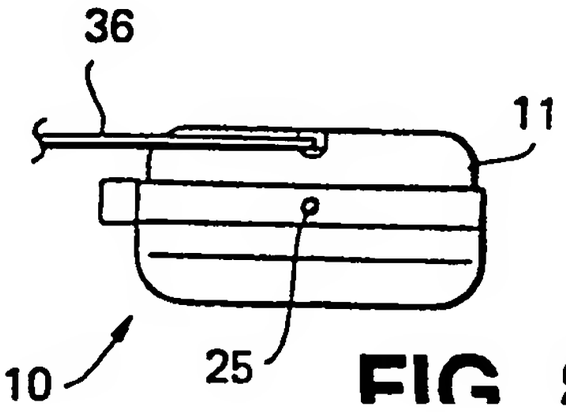

FIG. 8

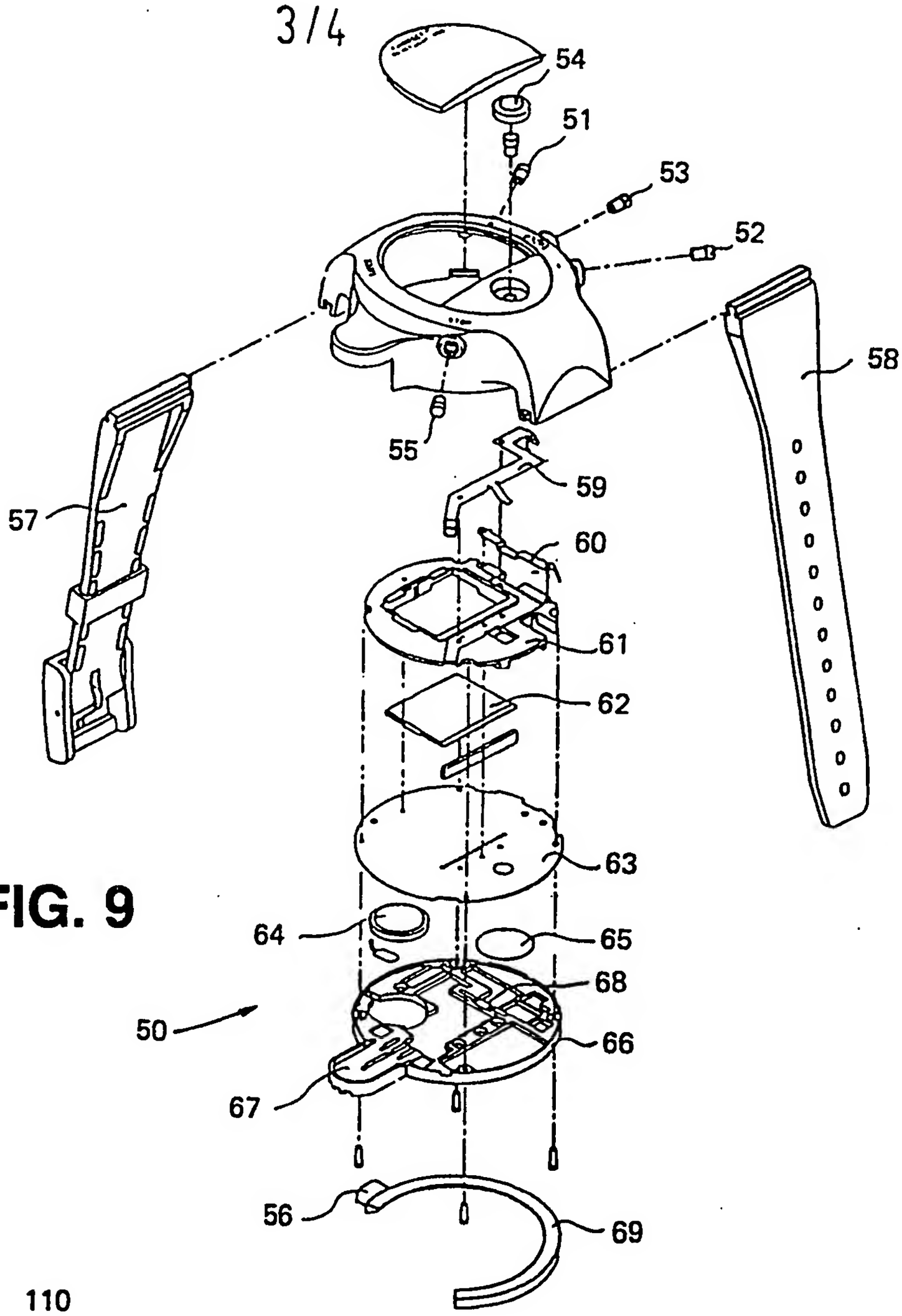
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FIG. 9

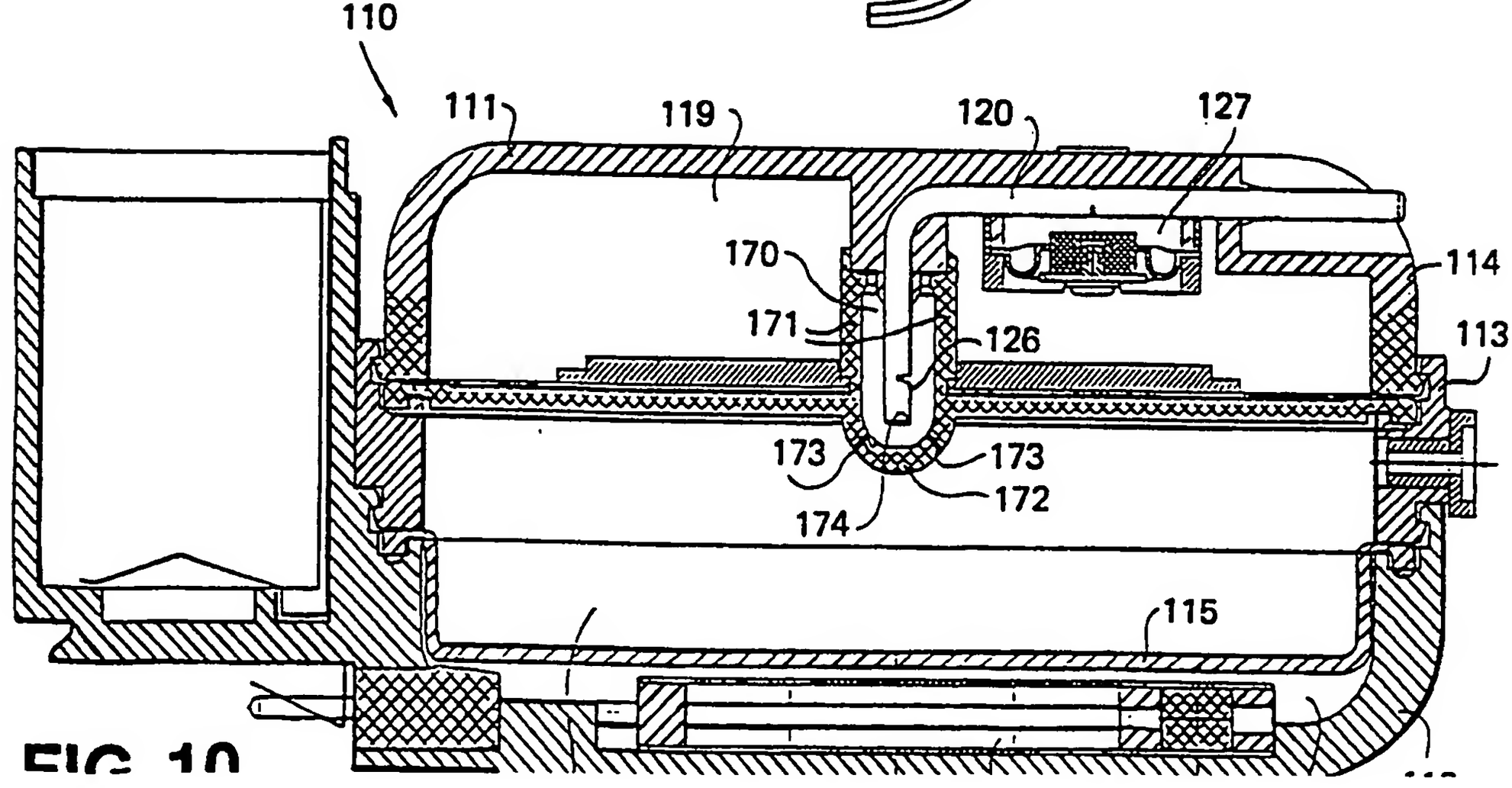
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FIG. 10

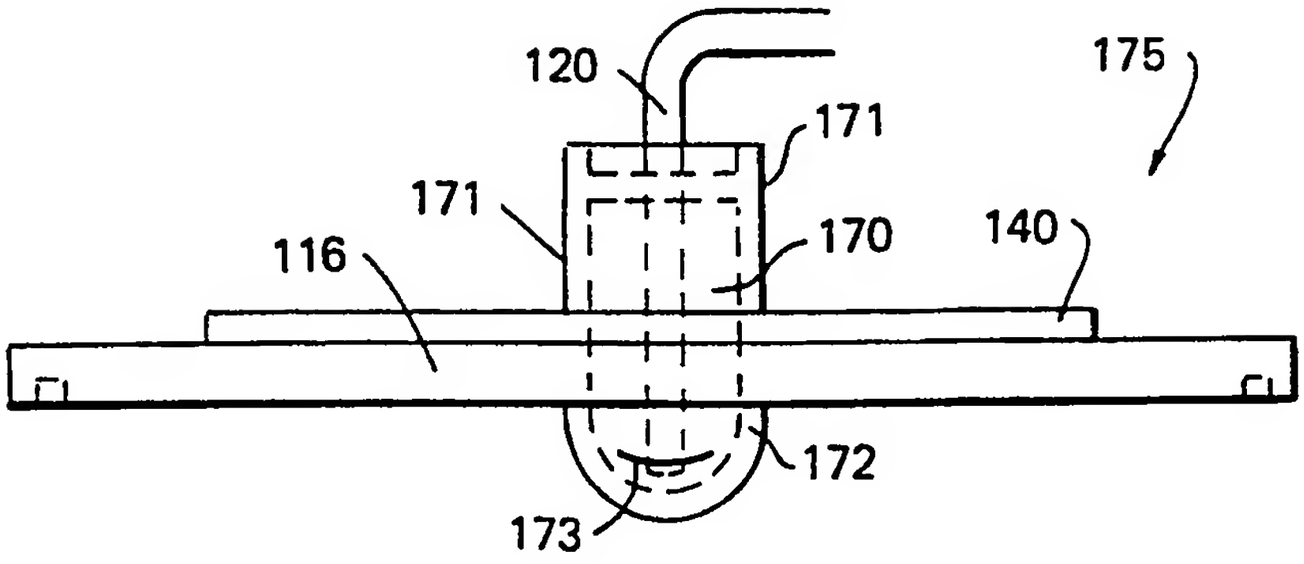

FIG. 11

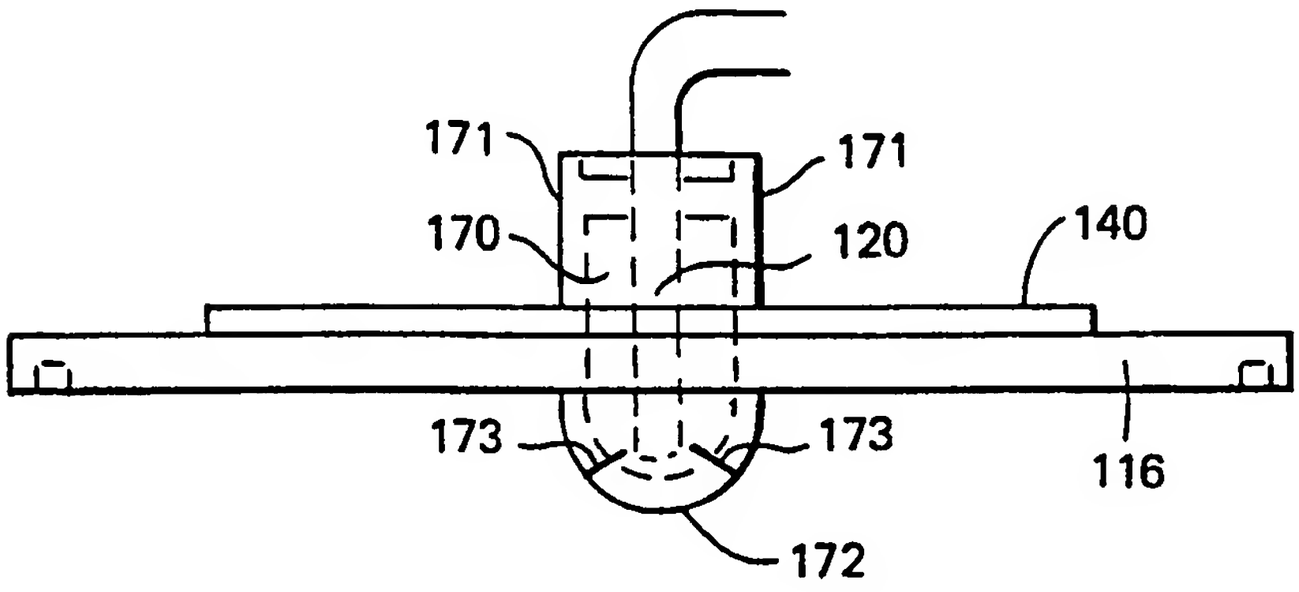

FIG. 12

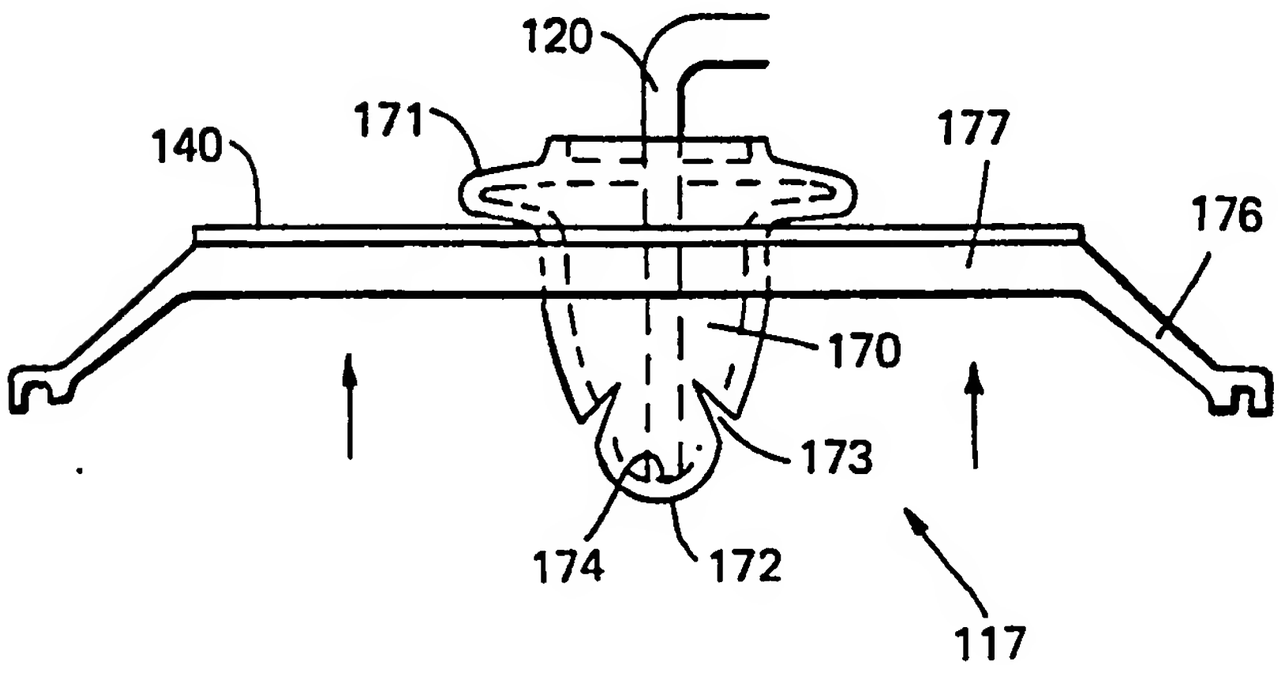

FIG. 13

Inter...onal Application No
PCT/IE 95/00031

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61M5/168 A61M5/155 G01P13/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61M G01P

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X Y	US,A,4 714 462 (DIDOMENICO) 22 December 1987 see column 6, line 63 - column 7, line 11; figures	1,4,5,8, 11-15 2,3,6,7, 9,10
Y	US,A,5 242 406 (GROSS ET AL) 7 September 1993 cited in the application see the whole document	2,3,9,10
Y	EP,A,0 241 791 (INTERMES SPA) 21 October 1987 see page 4, line 21 - page 5, line 21; figures	6,7

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
17 August 1995	04.09.95

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax (+31-70) 340-3016	Clarkson, P

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